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Bernardo Caycedo
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Patent
Attorney's Docket No. 031201-009

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

UTILITY PATENT
APPLICATION TRANSMITTAL LETTER

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Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Enclosed for filing is the utility patent application of Michael D. Laufer for METHOD AND APPARATUS FOR TREATING SMOOTH MUSCLES IN THE WALLS OF BODY CONDUITS .

Also enclosed are:

[X] 4 sheet(s) of [ ] formal [X] informal drawing(s);

[X] Other: Return Postcards.

The declaration of the inventor(s) [X] also is enclosed.

The filing fee has been calculated as follows:

CLAIMS					
	NO. OF CLAIMS		**EXTRA CLAIMS**	**RATE**	**FEE**
Basic Application Fee					$790.00
Total Claims	49	MINUS 20 =	29	x $22.00	$638.00
Independent Claims	9	MINUS 3 =	6	x $82.00	$492.00
If multiple dependent claims are presented, add $270.00					
Total Application Fee					$1,920.00
If verified Statement claiming small entity status is enclosed, subtract 50% of Total Application Fee					$00.00
Add Assignment Recording Fee of $40.00 if Assignment document is enclosed					
TOTAL APPLICATION FEE DUE					**$1,920.00**

[X] A check in the amount of $ 1,920.00 is enclosed for the fee due.

Please address all correspondence concerning the present application to:

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The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in triplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: June 10, 1998

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METHOD AND APPARATUS FOR TREATING SMOOTH MUSCLES IN THE WALLS OF BODY CONDUITS

BACKGROUND OF THE INVENTION

Field of the Invention

The invention relates to a method and apparatus for treating smooth muscle in the walls of body conduits, and more particularly, the invention relates to a method for treating medical conditions by reducing the bulk of smooth muscle surrounding a body conduit with radiant energy treatment of the smooth muscle.

Brief Description of the Related Art

Asthma is a disease which involves heightened reactivity of the tracheobronchial tree to numerous stimuli causing contraction of smooth muscle surrounding the airways of the lungs. The hyperreactivity of the airways can result from abnormal tissue reactions in the airways, which may be immunologically induced, or from a biochemical or neurohumoral imbalance of other normally functioning responses. In a healthy patient, the smooth muscle surrounding the airways contracts, such as when the patient coughs, to increase the localized airflow through the airways and expel inhaled particles which enter the lungs. In a patient with asthma, the airways are hyperreactive. With these hyperreactive airways a very small amount of pollen, allergen, or other material in the air will stimulate a large amount of smooth muscle contraction or spasm. This repeated contraction of the smooth muscles exercises the muscle causing the

muscle to hypertrophy and become larger. Because the tissue surrounding the smooth muscle is relatively rigid, the hypertrophied smooth muscle expands into the airways shrinking the inner diameter of the airways for passage of air. For example, a healthy person has smooth muscle thicknesses surrounding the airways of about 0.01 mm while the smooth muscle thickness in an asthma patient may enlarge to up to about 2 or 3 mm. Correspondingly, the inner diameter of the airways may be reduced from about 2 to 3 mm for a healthy person to about 0.5 mm or less for an asthma patient. This narrowing of the airways causes the whistling or wheezing sound associated with asthma.

Asthma is also characterized by the excessive secretion of mucus by glands lining the airways. The disease is currently treated by inhalation of bronchodilating drugs to enlarge the airways and atropine and similar compounds to reduce mucus secretion. Bronchodilating drugs are typically beta agonists which react with beta receptors in the smooth muscle causing the smooth muscle to relax, opening the airways. However, if the smooth muscle is already hypertrophied and enlarged the bronchodilating drugs which cause the muscle to relax do little to increase the airway inner diameter.

An additional disadvantage of the inhaled asthma drugs is that these drugs must be used repeatedly and regularly. Even with regular use of asthma drugs, patients frequently require hospitalization for more intensive therapy and sometimes die from severe bronchospasms and mucus plugging.

Accordingly, it would be desirable to provide an asthma treatment which enlarges the airways and reduces mucus plugging without the need for repetitive drug treatments.

In addition to the airways of the lungs, other body conduits such as the esophagus, ureter, urethra, and coronary arteries, are also subject to periodic spasms which cause hypertrophy of the smooth muscle around these body conduits reducing the inner diameter of the conduits.

SUMMARY OF THE INVENTION

The present invention relates to a device and method for treating bodily conduits by application of radiant energy to the smooth muscle tissue of the conduit walls to prevent the smooth muscle tissue from replicating. The treatment of the smooth muscle tissue causes a reduction in the amount of smooth muscle tissue over time which increases the inner diameter of the body conduit and prevents smooth muscle spasms.

In accordance with one aspect of the present invention, an apparatus for the treatment of body conduits includes an elongated body configured to be inserted into a body conduit, the elongated body having a proximal end and a distal end, and a source of energy for emitting energy from the elongated body in an intensity which, when applied to walls of the body conduit causes a change in smooth muscle tissue which prevents the smooth muscle tissue from replicating.

In accordance with another aspect of the present invention, an apparatus for the treatment of walls of airways in a patient's lungs includes an elongated body configured to be inserted into the airways of a patient's lungs, the device having a proximal end and a distal end, and a source of energy for emitting energy from the distal end of the elongated body in an intensity which, when applied to the walls of the airway causes a change in smooth muscle tissue which prevents the smooth muscle tissue from replicating.

When the source of energy is a light source the apparatus further includes a light transmitting fiber extending from the proximal end to the distal end of the elongated body for transmitting light from the light source into the patient's lungs, a connector on the distal end of the elongated body for connecting the elongated body to the source of light, and a light directing member positioned at a distal end of the elongated device for diffusing or redirecting the light from the light transmitting fiber in a substantially radial pattern from the distal end of the

elongated device.

In accordance with an additional aspect of the present invention, a method of treating asthma to control bronchospasms includes irradiating the walls of an airway in a lung in a wavelength and intensity which causes a change in smooth muscle tissue cells and prevents the smooth muscle tissue cells from replicating, and controlling bronchospasms by reduction or elimination of smooth muscle tissue.

In accordance with a further aspect of the invention, a method of treating respiratory conditions to control mucus plugging includes irradiating the walls of an airway in a lung in a wavelength and intensity which causes a change in mucus gland cells and prevents the mucus gland cells from replicating, and preventing mucus plugging by reduction or elimination of mucus glands.

In accordance with another aspect of the present invention, a method of treating an esophagus, an ureter, or an urethra to control spasms includes irradiating the walls of a conduit to cause a change in smooth muscle cells and prevent the smooth muscle cells from replicating.

The present invention provides advantages of a treatment for asthma or other enlargement or spasm of the smooth muscle by irradiation. The treatment enlarges airways, reduces or eliminates mucus plugging, and reduces or eliminates bronchospasm.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described in greater detail with reference to the preferred embodiments illustrated in the accompanying drawings, in which like elements bear like reference numerals, and wherein:

FIG. 1 is a side cross sectional view of a body conduit and an apparatus for treating the body conduit;

FIG. 2 is a schematic side view of lungs being treated with the treatment device;

FIG. 3 is a side cross sectional view of a distal end of a first embodiment of a treatment device according to the present invention;

FIG. 4 is a side cross sectional view of a distal end of a second embodiment of a treatment device according to the present invention;

FIG. 5 is a side cross sectional view of a distal end of a third embodiment of a treatment device according to the present invention;

FIG. 6 is a side cross sectional view of a fourth embodiment of a treatment device according to the present invention;

FIG. 7 is a side cross sectional view of a fifth embodiment of a treatment device according to the present invention;

FIG. 8 is a side cross sectional view of a sixth embodiment of a treatment device according to the present invention;

FIG. 9 is a cross sectional view of an airway in a healthy patient; and

FIG. 10 is a cross sectional view of an airway in an asthma patient.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 illustrates an energy delivery device 10 for the delivery of light energy to the walls 12 of a body conduit. The energy delivery device 10 includes an outer catheter or sheath 16 surrounding a light transmitting fiber 18. A light directing member 20 is positioned at a distal end of the energy delivery device 10 for directing the light to the conduit walls. Although the present invention will be described in detail with respect to the treatment of airways in the lungs, it should be understood that the present invention may also be used for treatment of other body conduits.

The energy delivery device 10 and method according to the present invention provide a more permanent treatment for asthma than the currently used bronchodilating drugs and drugs for reducing mucus secretion. In asthma patients,

the cross sectional diameter of the airways are reduced due to bulking of the smooth muscle surrounding the airways. FIG. 9 illustrates an airway 50 of a healthy individual. The airway is surrounded by smooth muscle tissue 52 which is capable of contracting to shrink the diameter of the airway. A plurality of mucus glands 54 are positioned around the airway 50 and secrete mucus into the airway. FIG. 10 illustrates an airway 60 in an asthma patient in which the smooth muscle 62 has hypertrophied increasing the thickness of the smooth muscle and reducing the inner diameter of the airway. The energy delivery device 10 of the present invention is used to debulk or reduce the volume of smooth muscle 62 surrounding the airway 60 of an asthma patient and increase the airway diameter for improved air exchange.

The energy delivery device 10 is used to irradiate the smooth muscle surrounding the airways causing the DNA of the smooth muscle cells to become cross linked. The treated smooth muscle cells with cross linked DNA are incapable of replicating. Accordingly, over time, as the smooth muscle cells die, the total thickness of smooth muscle decreases because of the inability of the cells to replicate. The programmed cell death causing a reduction in the volume of tissue is called apoptosis. This treatment does not cause an immediate effect but causes shrinking of the smooth muscle and opening of the airway over time and substantially prevents regrowth. The irradiation by the energy delivery device 10 of the walls of the airway also causes a cross linking of the DNA of the mucus gland cells preventing them from replicating and reducing mucus plugging over time.

As shown in FIG. 2, the energy delivery device 10 is an elongated device such as a catheter containing a fiber optic. The energy delivery device 10 is connected by a conventional optical connection to a light source 22. The treatment of an airway with the energy delivery device 10 involves placing a visualization system such as an endoscope or bronchoscope into the airways. The

energy delivery device 10 is then inserted through or next to the bronchoscope or endoscope while visualizing the airways. The energy delivery device 10 which has been positioned with a distal end within an airway to be treated is energized so that radiant energy is emitted in a generally radially direction from a distal end of the energy delivery device. The distal end of the energy delivery device 10 is moved through the airway in a uniform painting like motion to expose the entire length of an airway to be treated to the energy. The energy delivery device 10 may be passed along the airway one or more times to achieve adequate treatment. The painting like motion used to exposed the entire length of an airway to the energy may be performed by moving the entire energy delivery device 10 from the proximal end either manually or by motor.

The energy used may be coherent or incoherent light in the range of infrared, visible, or ultraviolet. The light source 22 may be any known source, such as a UV laser source. Preferably the light is ultraviolet light having a wavelength of about 240-280 nm or visible light in the red visible range. The intensity of the light may vary depending on the application. The light intensity should be bright enough to penetrate any mucus present in the airway and penetrate the smooth muscle cells and mucus gland cells to cause cross linking of the cell DNA. The light intensity may vary depending on the wavelength used, the application, the thickness of the smooth muscle, and other factors. Alternatively, a beta or gamma radiation source may be used instead of the light source as described in further detail below with respect to FIGS. 7 and 8.

FIGS. 3 - 6 illustrate different exemplary embodiments of the distal tip of the energy delivery device 10 for irradiating the airway walls. In FIG. 3, the sheath 16 includes a plurality of windows 24 which allow the energy which has been redirected by the light directing member 20 to pass substantially radially out of the sheath. The light directing member 20 is fitted into the distal end of the sheath 16. The light directing member 20 is a parabolic diffusing mirror having a

reflective surface 26 which is substantially parabolic in cross section. The light passes from the light source along the light transmitting fiber 18 and is reflected by the reflective surface 26 of the light directing member 20 through the windows 24. The windows 24 are preferably a plurality of energy transmitting sections spaced around the distal end of the sheath. The windows 24 may be open bores extending through the sheath 16. Alternatively, the windows 24 may be formed of a material transparent to the energy being used which allows the energy to pass out of the sheath 16.

FIG. 4 illustrates an alternative embodiment of the energy delivery device 10 in which the light directing member 20 has a conical shaped reflective surface 32. This conical shaped reflective surface may be formed at any desired angle which directs the light transmitted by the light transmitting fiber 18 radially out of the sheath 16. The use of a conical reflective surface 32 creates a light delivery pattern in which the light rays are directed in a generally coherent radial pattern which is at a generally fixed angle with respect to a longitudinal axis of the light delivery device. In contrast, the light delivery device of FIG. 3 with the parabolic reflective surface 26 directs light in a diverging radial pattern which will illuminate a larger area of the airway walls.

FIG. 5 illustrates a further alternative embodiment of the invention in which the light directing member 20 is a substantially conical member including concave reflective surfaces 36. These concave reflective surfaces 36 direct the light which passes in a generally parallel arrangement through the light transmitting fiber 18 out of the sheath 16 in a converging or crossing pattern. In addition, in the embodiment of FIG. 5, the windows have been replaced by a tip 38 of the sheath 16 formed of a material which is transparent to the energy being used.

The light directing members 20 having a reflective surface as illustrated in FIGS. 3-5 may be formed in any of the known manners, such as by coating a molded member with a reflective coating, such as aluminum or silver.

As an alternative to the reflective light directing members of FIGS. 3 - 5, a diffusing lens 42, such as a Teflon lens, may be positioned at the end of the light transmitting fiber 18 as illustrated schematically in FIG. 6. The diffusing lens 42 may direct the light from the light transmitting fiber 18 in a generally conical pattern as shown in FIG. 6. Alternatively, the diffusing lens 42 may direct the light in a more radially oriented pattern with the light rays being prevented from exiting the lens in a direction substantially parallel with the longitudinal axis of the light transmitting fiber 18 by a reflective or blocking member. In the embodiment of FIG. 6, the sheath 16 surrounding the light transmitting fiber 18 and the diffusing lens 42 may be eliminated entirely and the lens may be affixed directly to the end of the fiber.

According to one alternative embodiment of the invention, the energy delivery device 10 can be used in conjunction with photo-activatable substances such as those known as psoralens. These light activatable compounds, when activated, enhance the ability of light to cross link the DNA in the smooth muscle tissue and mucus glands. The light activatable compound may by injected intravenously. The light delivered by the light delivery device 10 is matched to the absorption spectrum of the chosen light activatable compound such that the light exposure activates the compound. When such light activatable substances are employed, a lower light intensity may be used to achieve cross linking of the DNA than the light intensity required to achieve cross linking without the light activatable compounds.

FIG. 7 illustrates an alternative embodiment of an energy delivery device 10 including an elongated body or shaft 66 having a radiation source 68 positioned at the distal end of the flexible shaft. The radiation source 68 may be any known

source of radiation such as a radioactive pellet of irridium. The treatment of a bodily conduit of a patient with the energy delivery device 10 of FIG. 7 is performed by moving the elongated shaft 66 back and forth in the body conduit in a painting like motion to cause a cross linking of the DNA in the smooth muscle surrounding the body conduit.

FIG. 8 illustrates another alternative embodiment of an energy delivery device 10 having a source of radiation such as a radioactive pellet 72 positioned within a cannula 74. According to this embodiment, in addition to moving the cannula itself to achieve a painting action withing a body conduit, the pellet 72 may be moved within the cannula 74. Movement of the radioactive pellet 72 may be performed by connecting a syringe to a proximal end of the cannula 74 and injecting or withdrawing fluid through the cannula to move the pellet in a piston like manner. A vent port 76 is provided at the distal end of the cannula 74 to allow fluid to pass into and out of the cannula. In use, the energy delivery device 10 of FIGS. 7 and 8 are preferably delivered to a treatment site within the body through a shielded cannula which prevents radiation from being emitted into surrounding tissue as the device is inserted.

In use, the embodiment of FIG. 8 is inserted to a treatment site such as an airway of the lungs through a radiation shielding cannula. A syringe filled with air is then connected to the proximal end of the cannula 74 and air is injected and withdrawn to move the radioactive pellet within the cannula 74 to expose a desired section of the airway to radiation emitted from the radioactive pellet. Once the treatment has been completed, the cannula 74 and pellet 72 are retracted inside the shielding cannula and the device is withdrawn from the patient.

The cross linking of the smooth muscle and mucus gland DNA according to the present invention will reduce or eliminate the smooth muscle and the secreting glands such as mucus glands from the area of the airway which is treated by preventing the treated cells from replicating. This light treatment provides

improved long term relief from asthma symptoms for some asthma sufferers. However, over time, some amount of smooth muscle or mucus gland cells which were not affected by an initial light treatment may regenerate and treatment may have to be repeated after a period of time such as one or more months or years.

Although the present treatment has been described for use in debulking enlarged smooth muscle tissue to open up the airways, it may also be used for eliminating smooth muscle altogether. The elimination of the smooth muscle tissue prevents the hyperreactive airways of an asthma patient from contracting or spasming, completely eliminating this asthma symptom.

The light delivery device 10 may also be used for treatment of other conditions by reducing the volume of smooth muscle tissue surrounding other body conduits. For example, the treatment system may be used for reducing smooth muscle and spasms of the esophagus of patients with achalasia or esophageal spasm, in coronary arteries of patients with Printzmetal's angina variant, for ureteral spasm, for urethral spasm, and irritable bowel disorders.

While the invention has been described in detail with reference to the preferred embodiments thereof, it will be apparent to one skilled in the art that various changes and modifications can be made and equivalents employed, without departing from the present invention.

WHAT IS CLAIMED IS:

1. An apparatus for the treatment of body conduits, the apparatus comprising:

an elongated body configured to be inserted into a body conduit, the elongated body having a proximal end and a distal end; and

a source of energy for emitting energy from the elongated body in an intensity which, when applied to walls of the body conduit causes a change in smooth muscle tissue which prevents the smooth muscle tissue from replicating.

2. The apparatus of Claim 1, wherein the source of energy is a source of light energy and the apparatus further comprises:

a light transmitting fiber extending from the proximal end to the distal end of the elongated body for transmitting light into the body conduit;

a connector on the distal end of the elongated body for connecting the elongated body to the source of light energy; and

a light directing member positioned at a distal end of the elongated device for diffusing or redirecting the light from the light transmitting fiber in a substantially radial pattern from the distal end of the elongated device.

3. The apparatus of Claim 2, wherein the source of light delivers light having a wavelength of about 240 nm to about 280 nm.

4. The apparatus of Claim 2, wherein the source of light delivers light in the red visible range.

5. The apparatus of Claim 1, wherein the source of energy delivers energy having a wavelength and intensity which, when applied to the walls of the body conduit crosslinks DNA in smooth muscle cells surrounding the conduit and prevents the smooth muscle cells from replicating.

6. The apparatus of Claim 2, wherein the light directing member includes a substantially conical reflective surface which redirects light from the light transmitting fiber in a direction away from a longitudinal axis of the fiber.

7. The apparatus of Claim 6, wherein the reflective surface is concave in cross section.

8. The apparatus of Claim 6, wherein the reflective surface is substantially planar in cross section.

9. The apparatus of Claim 6, wherein the reflective surface is substantially parabolic in cross section.

10. The apparatus of Claim 2, wherein the light directing member includes a diffusing lens which directs light from the transmitting fiber in a direction away from a longitudinal axis of the fiber.

11. The apparatus of Claim 2, wherein the light transmitting fiber is surrounded by a sheath for delivery to the airway.

12. The apparatus of Claim 11, wherein the sheath includes a distal end section which is transparent to the energy emitted by the light source.

13. The apparatus of Claim 11, wherein the sheath includes a distal section having a plurality of windows which are transparent to the energy emitted by the light source to allow the light which has been redirected by the light directing member to exit the sheath.

14. The apparatus of Claim 1, wherein the source of energy is a radioactive pellet positioned at the distal end of the elongated body.

15. The apparatus of Claim 1, wherein the source of energy is a radioactive pellet which is movable longitudinally within the elongated body to treat the body conduit.

16. An apparatus for the treatment of walls of airways in a patient's lungs, the apparatus comprising:

an elongated body configured to be inserted into the airways of a patient's lungs, the device having a proximal end and a distal end;

a source of energy for emitting energy from the distal end of the elongated body in an intensity which, when applied to the walls of the airway causes a change in smooth muscle tissue which prevents the smooth muscle tissue from replicating.

17. The apparatus of Claim 16, wherein the source of energy is a light source and the apparatus further comprises:

a light transmitting fiber extending from the proximal end to the distal end of the elongated body for transmitting light from the light source into the patient's lungs;

a connector on the distal end of the elongated body for connecting the elongated body to the source of light; and

a light directing member positioned at a distal end of the elongated device for diffusing or redirecting the light from the light transmitting fiber in a substantially radial pattern from the distal end of the elongated device.

18. The apparatus of Claim 16, wherein the source of energy delivers energy having a wavelength and intensity which, when applied to the walls of the airway crosslinks DNA in smooth muscle cells surrounding the airway and prevents the smooth muscle cells from replicating.

19. The apparatus of Claim 16, wherein the source of energy delivers energy having a wavelength and intensity which, when applied to the walls of the airway crosslinks DNA in mucus gland cells surrounding the airway and prevents the mucus gland cells from replicating.

20. An apparatus for the treatment of walls of an esophagus, the apparatus comprising:

an elongated body configured to be inserted into the esophagus, the elongate body having a proximal end and a distal end; and

a source of energy for emitting energy from the elongated body in an intensity which, when applied to the walls of the esophagus causes a change in smooth muscle tissue which prevents the smooth muscle tissue from replicating.

21. The apparatus according to Claim 20, wherein the source of energy is a light source and further comprising:

a light transmitting fiber extending from the proximal end to the distal end of the elongated body for transmitting light into the esophagus;

a connector on the distal end of the elongated body for connecting the elongated body to the source of light; and

a light directing member positioned at a distal end of the elongated device for diffusing or redirecting the light from the light transmitting fiber in a substantially radial pattern from the distal end of the elongated device.

22. The apparatus of Claim 21, wherein the light source delivers light having a wavelength of about 240 nm to about 280 nm, or delivers light in the red visible range.

23. The apparatus of Claim 20, wherein the source of energy is a radioactive pellet positioned within the elongated body.

24. An apparatus for treatment of walls of a ureter or urethra, the apparatus comprising:

an elongated body configured to be inserted into the ureter or urethra, the device having a proximal end and a distal end; and

a source of energy for emitting energy from the elongated body in an intensity which, when applied to the walls of the ureter or urethra causes a change in smooth muscle tissue which prevents the smooth muscle tissue from replicating.

25. The apparatus of Claim 24, wherein the source of energy is a light source and further comprising:

a light transmitting fiber extending from the proximal end to the distal end of the elongated body for transmitting light into the ureter or urethra;

a connector on the distal end of the elongated body for connecting the elongated body to the source of light; and

a light directing member positioned at a distal end of the elongated device for diffusing or redirecting the light from the light transmitting fiber in a substantially radial pattern from the distal end of the elongated device.

26. The apparatus of Claim 25, wherein the light source delivers light having a wavelength of about 240 nm to about 280 nm, or delivers light in the red visible range.

27. The apparatus of Claim 24, wherein the source of energy is a radioactive pellet positioned within the elongated body.

28. A method of treating asthma to control bronchospasms, the method comprising:

irradiating the walls of an airway in a lung in a wavelength and intensity which causes a change in smooth muscle tissue cells and prevents the smooth muscle tissue cells from replicating; and

controlling bronchospasms by reduction or elimination of smooth muscle tissue.

29. The method of Claim 28, wherein the irradiation of the walls is performed by emitting a light energy having a wavelength of about 240 nm to about 280 nm.

30. The method of Claim 28, wherein the irradiation of the walls is performed by emitting light energy having a wavelength in the red visible range.

31. The method of Claim 28, wherein the irradiation of the walls is performed by exposing the walls to radiation emitted by a radioactive pellet.

32. The method of Claim 28, wherein the irradiation of the walls is performed by moving an energy delivery device along the airway.

33. A method of treating respiratory conditions to control mucus plugging, the method comprising:

irradiating the walls of an airway in a lung in a wavelength and intensity which causes a change in mucus gland cells and prevents the mucus gland cells from replicating; and

preventing mucus plugging by reduction or elimination of mucus glands.

34. The method of Claim 33, wherein the irradiation of the walls is performed by emitting a light energy having a wavelength of about 240 nm to about 280 nm.

35. The method of Claim 33, wherein the irradiation of the walls is performed by emitting light energy having a wavelength in the red visible range.

36. The method of Claim 33, wherein the irradiation of the walls is performed by exposing the walls to radiation emitted by a radioactive pellet.

37. The method of Claim 33, wherein the irradiation of the walls is performed by moving an energy delivery device along the airway.

38. A method of treating an esophagus to reduce achalasia or esophageal spasm, the method comprising:

irradiating the walls of an esophagus in a wavelength and intensity which causes a change in smooth muscle cells and prevents the smooth muscle cells from replicating; and

preventing spasms of the smooth muscle tissue by elimination or reduction of the smooth muscle tissue.

39. The method of Claim 38, wherein the irradiation of the walls is performed by emitting a light energy having a wavelength of about 240 nm to about 280 nm.

40. The method of Claim 38, wherein the irradiation of the walls is performed by emitting light energy having a wavelength in the red visible range.

41. The method of Claim 38, wherein the irradiation of the walls is performed by exposing the walls to radiation emitted by a radioactive pellet.

42. The method of Claim 38, wherein the irradiation of the walls is performed by moving an energy delivery device along the esophagus.

43. A method of treating an ureter or an urethra to control spasms, the method comprising:

irradiating the walls of an ureter or an urethra in a wavelength and intensity which causes a change in smooth muscle cells and prevents the smooth muscle cells from replicating; and

preventing spasms of smooth muscle tissue by elimination or reduction of the smooth muscle tissue.

44. The method of Claim 43, wherein the irradiation of the walls is performed by emitting a light energy having a wavelength of about 240 nm to about 280 nm.

45. The method of Claim 43, wherein the irradiation of the walls is performed by emitting light energy having a wavelength in the red visible range.

46. The method of Claim 43, wherein the irradiation of the walls is performed by exposing the walls to radiation emitted by a radioactive pellet.

47. The method of Claim 43, wherein the irradiation of the walls is performed by moving an energy delivery device along the ureter or urethra.

48. A method of training a person to treat a body conduit by irradiation comprising demonstrating or instructing the steps of:

irradiating walls of a body conduit with energy in wavelength and intensity which causes a change in smooth muscle tissue cells and prevents the smooth muscle tissue cells from replicating; and

controlling spasms of smooth muscle tissue by elimination or reduction in the smooth muscle tissue surrounding the body conduit.

49. The method of Claim 48, wherein the body conduit is selected from a group consisting of an airway in a lung, an esophagus, a ureter, and a urethra.

ABSTRACT OF THE DISCLOSURE

A device and method for treating bodily conduits involves the application of energy to the smooth muscle tissue of the conduit walls to reduce the bulk of smooth muscle tissue and mucus glands. The irradiation treatment of the smooth muscle tissue causes a reduction in the amount of smooth muscle tissue over time which increases the inner diameter of the body conduit for improved fluid flow and prevents smooth muscle spasms. The treatment is particularly useful in the lungs for treatment of asthma to prevent bronchospasms, increase the airway diameter for improved air exchange, and reduce mucus secretions in the lungs.

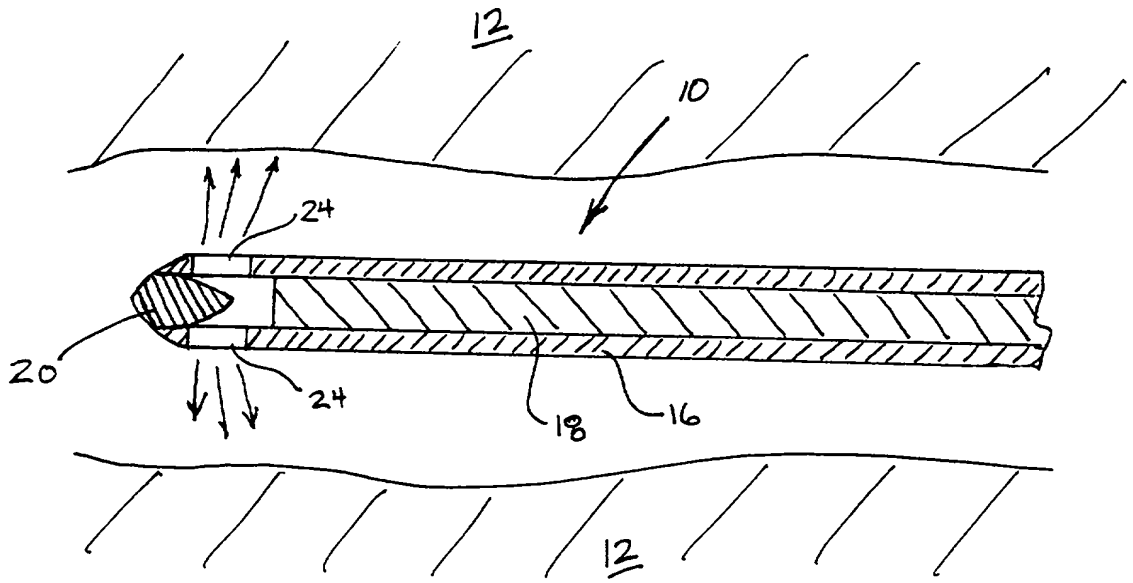

FIG. 1

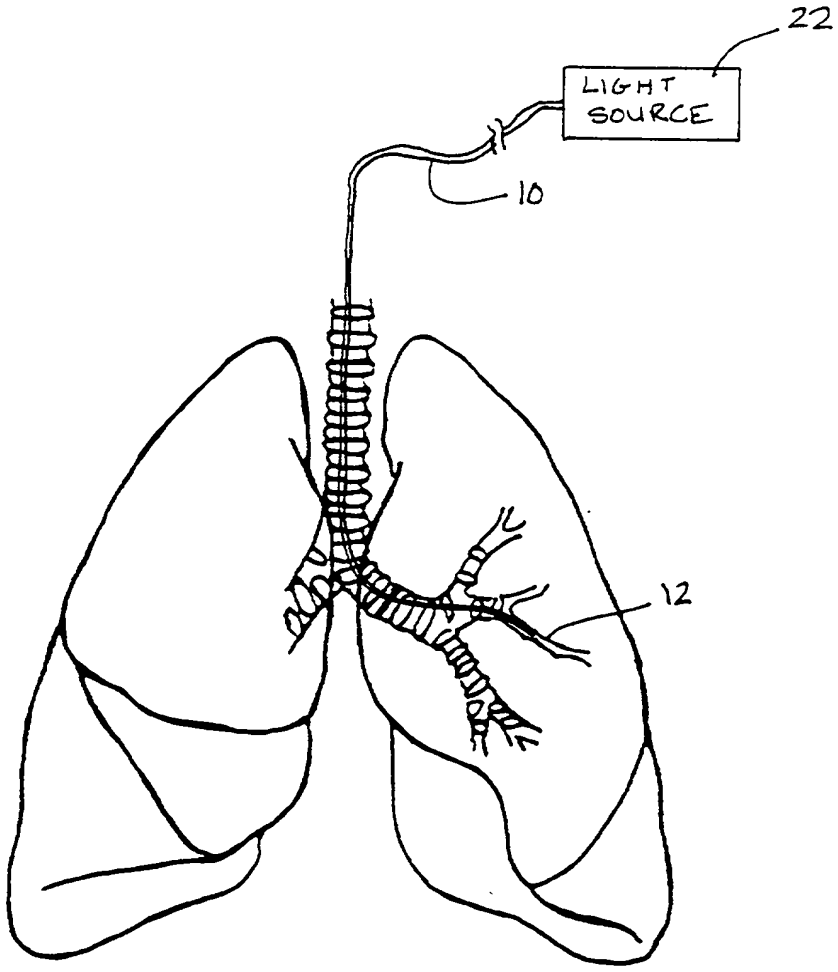

FIG. 2

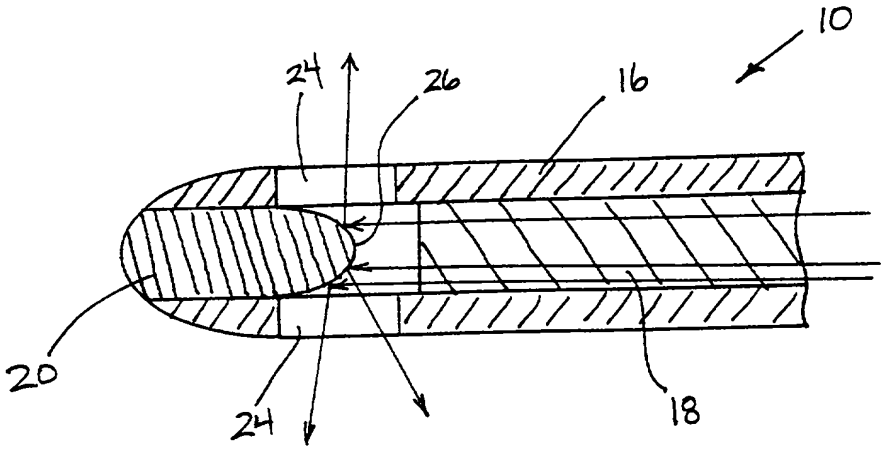

FIG. 3

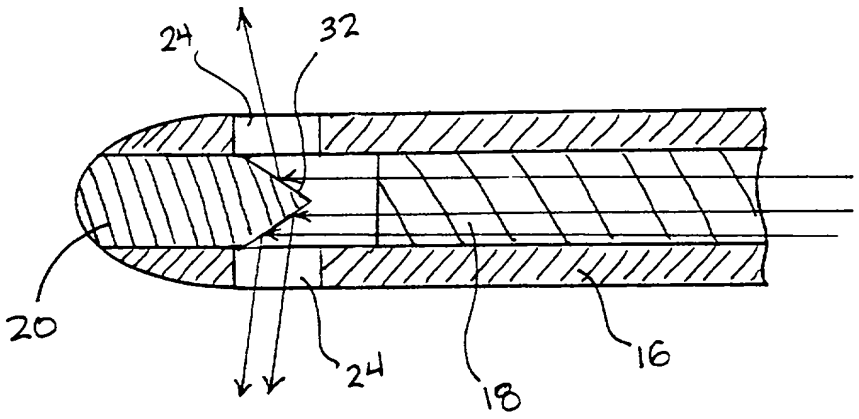

FIG. 4

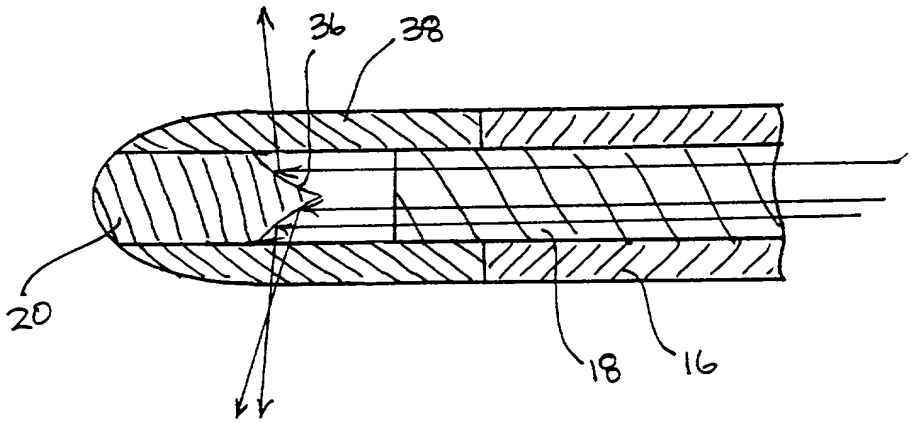

FIG. 5

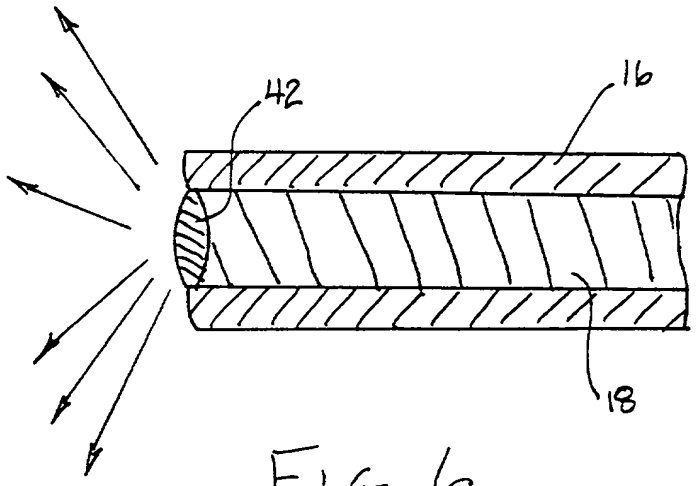

FIG. 6

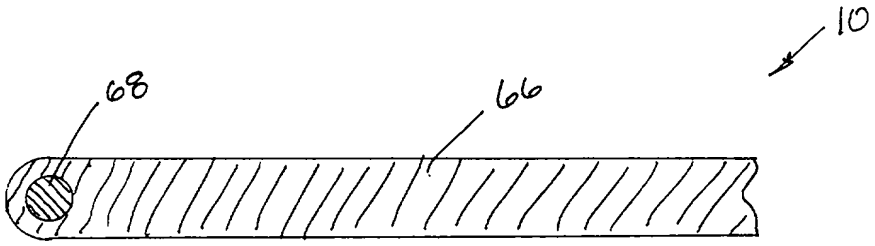

FIG. 7

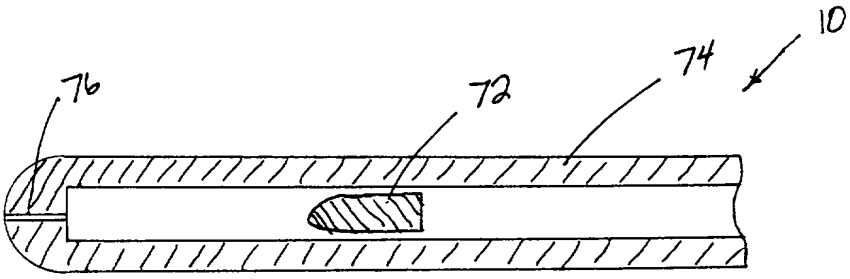

FIG. 8

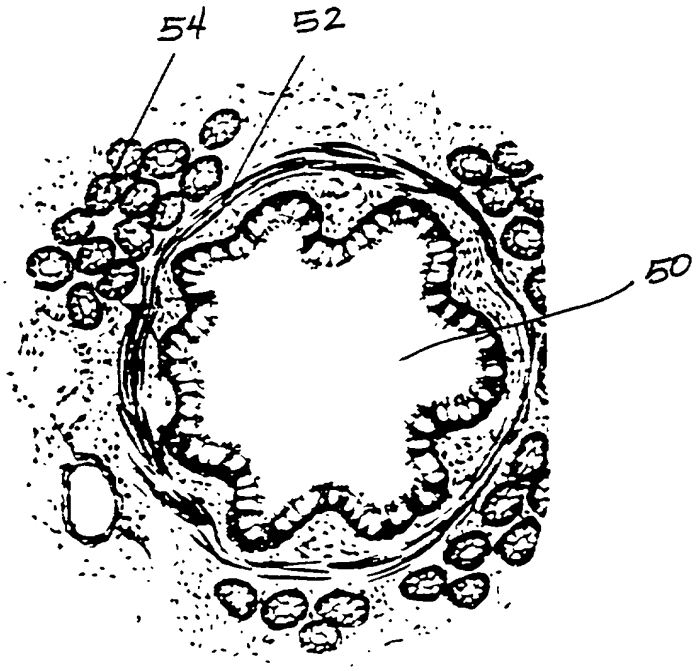

FIG. 9

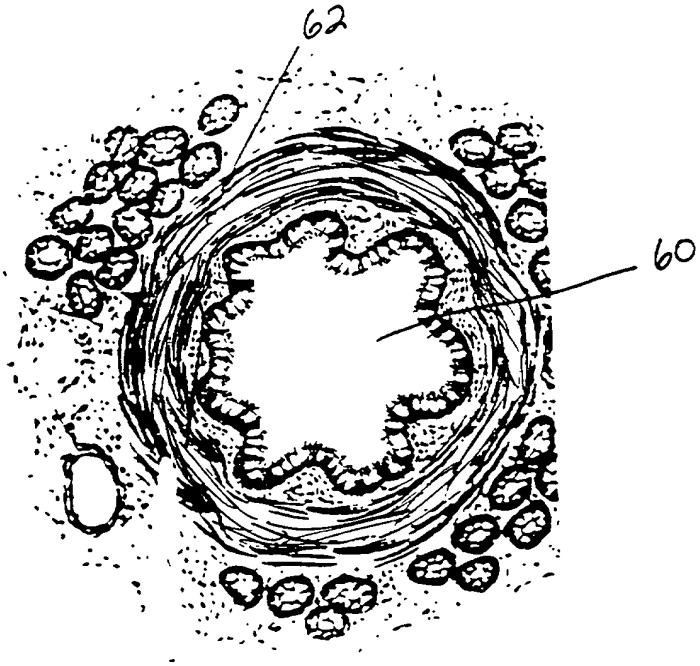

FIG. 10

COMBINED DECLARATION AND POWER OF ATTORNEY FOR UTILITY PATENT APPLICATION	Attorney's Docket No. 031201-009

As a below-named inventor, I hereby declare that:
My residence, post office address and citizenship are as stated below next to my name;
I BELIEVE I AM THE ORIGINAL, FIRST AND SOLE INVENTOR (if only one name is listed below) OR AN ORIGINAL, FIRST AND JOINT INVENTOR (if more than one name is listed below) OF THE SUBJECT MATTER WHICH IS CLAIMED AND FOR WHICH A PATENT IS SOUGHT ON THE INVENTION ENTITLED:

METHOD AND APPARATUS FOR TREATING SMOOTH MUSCLES IN THE WALLS OF BODY CONDUITS

the specification of which

(check one) ☒ is attached hereto;

☐ was filed on _____ as

Application No. _____

and was amended on _____; (if applicable)

I HAVE REVIEWED AND UNDERSTAND THE CONTENTS OF THE ABOVE-IDENTIFIED SPECIFICATION, INCLUDING THE CLAIMS, AS AMENDED BY ANY AMENDMENT REFERRED TO ABOVE;

I ACKNOWLEDGE THE DUTY TO DISCLOSE TO THE OFFICE ALL INFORMATION KNOWN TO ME TO BE MATERIAL TO PATENTABILITY AS DEFINED IN TITLE 37, CODE OF FEDERAL REGULATIONS, Sec. 1.56 (as amended effective March 16, 1992);

I do not know and do not believe the said invention was ever known or used in the United States of America before my or our invention thereof, or patented or described in any printed publication in any country before my or our invention thereof or more than one year prior to said application; that said invention was not in public use or on sale in the United States of America more than one year prior to said application; that said invention has not been patented or made the subject of an inventor's certificate issued before the date of said application in any country foreign to the United States of America on any application filed by me or my legal representatives or assigns more than twelve months prior to said application;

I hereby claim foreign priority benefits under Title 35, United States Code Sec. 119 and/or Sec. 365 of any foreign application(s) for patent or inventor's certificate as indicated below and have also identified below any foreign application for patent or inventor's certificate on this invention having a filing date before that of the application(s) on which priority is claimed:

COMBINED DECLARATION AND POWER OF ATTORNEY	Attorney's Docket No. 031201-009

COUNTRY/INTERNATIONAL	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED
			YES_ NO_
			YES_ NO_

I hereby appoint the following attorneys and agent(s) to prosecute said application and to transact all business in the Patent and Trademark Office connected therewith and to file, prosecute and to transact all business in connection with international applications directed to said invention:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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